II. REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. Claims 11 to 20 have been renumbered as 14 to 23 in order to correct a previous typographical error. After entry of these amendments, claims 1 and 23 are pending.

35 U.S.C. § 103

Claims 1 and 23 (renumbered; previously claim 20) stand rejected under 35 U.S.C. § 103 as allegedly unpatentable over Lackey et al. (Biochem. Pharma., 2001) in view of Applicant's alleged admission appearing on page 1, paragraph [0003] that the functions of tumor suppressor genes are a major focus of recent attempts to develop innovative therapeutics for the treatment of cancer. The Office further noted that Applicant allegedly admits that the functional loss of tumor suppressor genes has been linked to hyperproliferative inflammatory or autoimmune disease including rheumatoid arthritis that have cellular hyperproliferation as one of its characteristics.

The Office argued that Lackey et al. teaches that Applicant's active agent has cytotoxic activity against tumor cells. The Office particularly noticed that Lackey et al. teaches on page 181 under paragraph 2.7 that NB 1001 (a/k/a NB 1011) was administered in 1.25, 2.5 and 3.5 mg total dose/animal/day which is within Applicant's effective dosage set forth in claims 1 and 23 (renumbered; previously claim 20). The Office argued that it would have been obvious to one of skill in the art to employ NB 1011 for the treatment of rheumatoid arthritis because Applicant admits that rheumatoid arthritis and cancer both have the same cellular hyperproliferation characteristics and both of the disorders are related as losing functions of tumor suppressor genes. The Office also argued that one would have been motivated to employ NB 1011 for the treatment of rheumatoid arthrisis in order to target cellular hyperproliferation characteristics and avoid losing functions of tumor suppressor genes

in rheumatoid arthritis by administering cytotoxic, antitumor (antiproliferative) compound (NB 1011) as taught by Lackey.

Applicant respectfully traverses. Claims 1 and 23 (renumbered; previously claim 20) are directed to a method for treating a subject having rheumatoid arthritis comprising delivering to the subject an effective amount of an L- or D- compound of the formula:

or its 5' monophosphate derivative, and wherein the compound or its 5' monophosphate derivative may be in any of its enantiomeric, disasteriomeric, stereoisomeric or anomeric forms.

The Office's prima facie case under 35 U.S.C. § 103 fails on two grounds:

1) that Lackey et al. does not teach as broadly as alleged by the Office and 2) the
Office's prima facie rejection therefore lacks the motivation to combine the teachings of the references.

Lackey et al. notes that loss of tumor suppressor function and elevation or overexpression of certain genes <u>may contribute to chemo-resistance in tumor cells</u> <u>overexpressing TS</u>. Thus, Lackey et al. does not teach as broadly as the Office alleged. With respect to the combination of Lackey and Applicant's statements in the background section of the subject specification, Applicant does not state that functional

loss of tumor suppressor genes has been linked to chemo-resistant hyperproliferative cells. Thus, the Office has failed to provide a prima facie case of obviousness under 35 U.S.C. 103.

For these reasons, the rejection is improper and Applicant respectfully requests its withdrawal.

III. CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

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Respectfully submitted,

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